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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/649,293	08/28/2000	Lawrence T. Cohen	2447-012	7384

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/649,293

Applicant(s)

COHEN, LAWRENCE T.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☒ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 4/2, 5, 6-9, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described is the system and method having the patient have evenly spaced aural receptors disposed at equal distances and having an array with electrodes at different spacings and matching the position of the electrodes approximately to the locations of the evenly spaced receptors, in combination with the other elements and steps in the claims. The original specification deals with receptors on the inner wall being spaced closer together (uneven) and then having the electrodes spaced unevenly to match the unevenly spaced receptors (this can be seen on page 2, lines 14-17, page 4 lines 3-8, and figure 2). This rejection is related to new matter. It is noted for the conventional (prior art) system of figure 1, the equal interval receptors match the equal interval electrodes (page 3, lines 23-28).

Claims 2, 3, 4/2, 5, 6-9, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described is the system and method

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having the patient have evenly spaced aural receptors disposed at equal distances and having an array with electrodes at different spacings and matching the position of the electrodes approximately to the locations of the evenly spaced receptors, in combination with the other elements and steps in the claims. The specification deals with receptors on the inner wall being spaced closer together (uneven) and then having the electrodes spaced unevenly to match the uneven receptors (this can be seen on page 2, lines 14-17, page 4 lines 3-8, and figure 2). This rejection is related to enablement. It is noted for the conventional (prior art) system of figure 1, the equal interval receptors match the equal interval electrodes (page 3, lines 23-28).

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described is the method having a step of detecting the location of the evenly spaced aural receptors. The original specification does not have any step to the detection of the receptors. This rejection is related to new matter.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described is the method having a step of detecting the location of the evenly spaced aural receptors. The specification does not have any step to the detection of the receptors and it is unclear how these receptors are detected. This rejection is related to enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 4/2, 5, 6-9, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 13, and 14 are vague since it is unclear how the patient has evenly spaced receptors and the electrode array has different spacings between electrodes and then to approximately match the locations of the non-evenly spaced electrodes to the evenly spaced receptors.

In claim 14, "Cordi" is not spelled correctly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hochmair et al (4284856).

Claims 1, 4/1, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochmair-Desoyer et al ("An eight Channel Scala Tympani Electrode for Auditory Prostheses").

On page 46, the fourth full paragraph, Hochmair-Desoyer describes the spacing between contacts belonging to the same channel as 1.5 mm and between two neighboring contacts of different channels as 0.5 mm. Since the claim is a "comprising" claim (an opened ended claim) and since the claims do not specify which electrodes are being limited, but just use the broad

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term "electrodes", Hochmair-Desoyer meets the claim limitations since there will be different channel electrodes at the apical end 0.5 mm apart and same channel electrodes 1.5 mm apart at the basal end. In addition, the use of three consecutive electrodes (different channel and then same channel) will provide the claimed uniformly graduated electrodes. Finally, for claim 5, Hochmair-Desoyer states on page 45, that the contacts are placed as near to excitable nerve-structures as possible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4/1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochmair et al (4284865).

Hochmair discloses the claimed invention except for the spacing to be uniformly graduated between consecutive electrodes. Hochmair does disclose the schematic of the cochlea showing the frequency response, the use of at least four different frequency ranges, the stimulating of the lower frequency stimulation sites near the apex, and does disclose that the electrode contacts can be positioned on the device to stimulate a region of the cochlea for a desired frequency response and in accordance with the frequency response of the cochlea. This provides a clear suggestion that the spacing of the electrodes can be modified to change the distance between adjacent electrodes to have the spacing between adjacent electrodes at the apical end to be less than the spacing at the basal end, the spacing to be different in different

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regions, and the spacing to be uniformly graduated between consecutive electrodes to correspond to the a desired frequency response and in accordance with the frequency response of the cochlea. The determination of the most appropriate spacing of the electrodes by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Response to Arguments

Applicant's arguments filed 4/3/02 have been fully considered but they are not persuasive. Claims 6, 13, and 14 contain new matter, are not enabled, and are vague. It is unclear how the receptors are evenly spaced and the electrodes not evenly spaced and for the two to then approximately match up. The claims are mixing the prior art (conventional system) of figure 1 having evenly spaced receptors with the applicant's present invention of figure 2 of having the electrodes not evenly spaced. The argument that claim 1 recites that the electrodes are positioned along said electrode array to target the selected regions of the cochlea (and therefore implying that neither Hochmair reference performs this) is not persuasive since the Hochmair patent states that the electrodes are "selectively positioned in the cochlea to stimulate regions having a desired frequency response" and the Hochmair reference states that "the contacts are placed as near to excitable nerve-structures as possible" and both therefore meet the limitation of the electrodes being positioned to target selected regions of the cochlea. The argument that there is nothing in the Hochmair references to show that they recognized or appreciated the problem addressed by the present invention is not persuasive since the references meet the claim limitations presented. The argument that the references do not teach uneven spacing of electrodes is not persuasive. The Hochmair reference has a pair of electrodes at 1.5

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mm apart and the spacing between adjacent pairs as 0.5 mm apart, therefore providing uneven spacing when going from one pair to the next compared to an original pair. It is noted that the claim is an open ended "comprising" claim, and permits other electrodes to be included on the array. The Hochmair patent states that the electrodes can be adjusted to a desired frequency response and shows how the spacing of the frequency response of the ear is different and the determination of the most appropriate spacing, such as graduated spacing, by routine experimentation would be prima facie obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762

5/9/2

GRE
May 9, 2002